UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ANGELA OBERSTER AND DONALD OBERSTER Plaintiffs, v. EXACTECH, INC. and EXACTECH, US, INC. Defendants.	)	Civil Action No.: COMPLAINT & DEMAND FOR JURY TRIAL

NOW COMES Plaintiffs ANGELA OBERSTER AND DONALD OBERSTER (hereafter collectively referred to as "Plaintiffs"), by and through the undersigned attorneys, and brings this action against EXACTECH, INC. ("EXACTECH") and EXACTECH US, INC. ("EXACTECH US") (hereafter collectively referred to as "Defendants"), for personal injuries suffered as a proximate result of the implantation of the TRULIANT® Total Knee System (hereafter collectively referred to as the "Truliant Device" or "Device") and allege as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' development, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, storage, and/or selling of the Truliant Device. The Device as referred to in this Complaint includes the Truliant PS polyethylene Insert Tibial Insert.

2. Thousands of patients, like Plaintiff ANGELA OBERSTER (hereafter individually referred to as "Plaintiff"), have been, and/or will be, required to undergo extensive revision surgery to remove and replace Defendants' defective Devices due to a recent recall which first revealed to

patients and surgeons that the polyethylene components within the prosthesis prematurely degrades over time causing an inflammatory response resulting in bone necrosis (death), also known as osteolysis. The recall notice admits that the recall and problems arose from the failure to properly package the polyethylene insert component of the Devices.

3. As a result of Defendants' failure to properly package the Devices prior to distribution, the polyethylene liner prematurely degraded and Plaintiff required revision surgery due to severe pain, swelling, and instability in the knee and leg. These injuries were caused by early and preventable wear of the polyethylene insert and resulting component loosening and/or other failures including tissue damage, osteolysis, permanent bone loss, and other injuries.

4. Recipients of these Devices, like the Plaintiff, have been required to undergo revision surgeries well before the estimated life expectancy of a knee implant and at a much higher rate than should reasonably be expected for devices of this kind resulting in pain and disability leading up to and subsequent to the revision surgery.

5. Despite knowledge that the Devices were defective and resulted in premature failures and accompanying complications, Defendants only first issued a nationwide recall on February 7, 2022, advising the public that "most of our inserts since 2004 were packaged in out-of-specification… vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance."

6. As a direct and proximate result of the defective nature of Defendants' Device surgically implanted in Plaintiff, which necessitated premature removal of Plaintiff's TRULIANT® PS Polyethylene Tibial Insert, Plaintiff ANGELA OBERSTER suffered and will continue to suffer serious personal injuries, including pain, impaired mobility, rehabilitation, medical care, loss of enjoyment of life, and other medical and non-medical sequelae.

7. Plaintiffs bring this action for personal injuries suffered as a proximate result of the implantation and failure of the Truliant Device. Plaintiffs accordingly seek compensatory and punitive damages, and all other available remedies provided to Plaintiffs under the law as a result of injuries Plaintiff ANGELA OBERSTER sustained due to the Defendants' negligent, reckless, and wrongful conduct.

JURISDICTION & VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and all Defendants.

9. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of Ohio. At all relevant times Defendants transacted, solicited, and conducted business in the State of Ohio through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in the State of Ohio.

10. Venue is proper in this Judicial District and Division pursuant to 28 U.S.C. § 1391 because Plaintiffs are citizens and residents of Stark County, Ohio.

THE PARTIES

11. Plaintiffs ANGELA OBERSTER AND DONALD OBERSTER are residents and citizens of East Sparta, Ohio.

12. Defendant EXACTECH, INC. is a domestic, Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

13. Defendant EXACTECH, INC. develops, manufactures, packages, stores, distributes, markets, and sells orthopedic implant devices, including the Truliant Comprehensive

Total Knee System, and other related surgical instrumentation throughout the United States and the State of Ohio.

14. Defendant EXACTECH, INC. manufactured the Device implanted in Plaintiff ANGELA OBERSTER.

15. At all times relevant to this action, Defendant EXACTECH, INC. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Devices in interstate commerce, and throughout the State of Ohio, and generated substantial revenue as a result.

16. Defendant EXACTECH US, INC., a wholly owned subsidiary of Defendant EXACTECH, INC., is a domestic Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

17. According to public filings, Defendant EXACTECH US, INC., conducts Defendants' U.S. sales and distribution activities.

18. EXACTECH US, INC. is engaged in the business of designing, developing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing Defendants' products, including the Truliant Device described herein, into commerce throughout the United States and the State of Ohio.

19. Upon information and belief, the Truliant Devices manufactured by Defendant EXACTECH, INC. were distributed by Defendant EXACTECH US, INC. throughout the United States, including to the Crystal Clinic Orthopaedic Center in Akron, Ohio, where Plaintiff ANGELA OBERSTER received her implant.

20. At all times relevant to this action, Defendant EXACTECH US, INC., tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, stored,

promoted, advertised, marketed, distributed, and/or sold Truliant Devices in interstate commerce, and throughout the State of Ohio, and generated substantial revenue as a result.

FACTUAL BACKGROUND

21. Upon information and belief, the first Optetrak Total Knee System was available for implantation in 1994, building upon technology licensed from HSS.

22. Between 1994 and 2015, Defendants obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various Optetrak total knee system devices and components, including the OPTETRAK LOGIC® knee system and Optetrak Logic PSC Tibial Insert.

23. The Optetrak Total Knee System is classified as a knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. It features a mix of polyethylene and metal-based components.

24. According to Defendants, the Optetrak Device introduced "novel implants and instruments to make the total knee procedure easier, faster, and more consistent, improving patient satisfaction for a more diverse population requiring total knee replacements."

25. In 2017, Defendants expanded its portfolio by obtaining 510(k) clearance to market and sell the TRULIANT® Knee System which features a full medial-radius of curvature but utilizes the same polyethylene for the tibial insert.

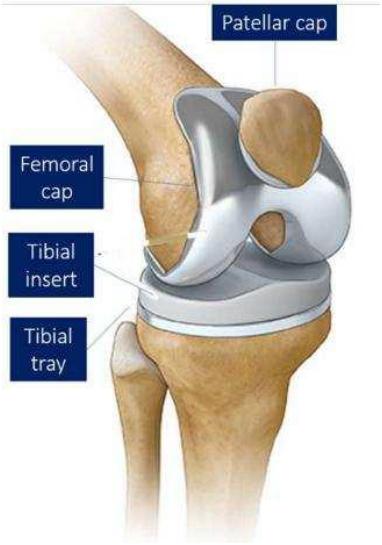
26. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

27. 510(k) clearance only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least 90 days prior to the device's introduction on the market, and

to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

28. All the component parts comprising of Plaintiff's Device were cleared for marketing by the FDA pursuant to the 510(k) process.

29. The Optetrak and Truliant Devices are comprised of the following parts: a patellar cap, femoral cap, tibial insert and tibial tray as shown below.



30. The patellar cap and tibial insert are made of polyethylene.

31. Since 1994, Defendants touted the Optetrak Device as being first-in-class in their product brochures.

32. In their marketing materials, Defendants promised that the Optetrak Device had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

33. Defendants promoted their Optetrak Devices as a system with nearly three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

34. However, Defendants' Optetrak Devices have performed poorly when compared to its competitors. For example, the Australian Orthopaedic Association, a preeminent, internationally recognized orthopedic implant registry, has identified the Optetrak as an implant with a higher-than-expected rate of revision.

35. According to the 2020 Australian National Joint Replacement Registry, the rate of revision for a total knee replacement utilizing an Optetrak tibial component with a Optetrak-CR femoral component was 8.5% at ten years and 10.2% at ten years when implanted with a Optetrak-PS femoral component, which far exceeds international guidelines for accepted revision rates.

36. Per the recommendations established by the International Benchmarking Working Group and applied by the Australian Orthopaedic Association, the Optetrak Devices do not qualify for a "superiority benchmark" or even a "non-inferiority benchmark."

37. At all times relevant, Defendants have been aware of a high rate of early failures associated with the Optetrak Device and were aware of such failures when Defendants obtained 510(K) clearance to market and sell the Truliant Device utilizing the same polyethylene tibial component.

38. Upon information and belief, by 2012, Defendants had further clinical evidence that its Devices were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicated instances of revision due to: "loose tibial component;" "aseptic loosening;" "pain and visible loosening;" "polyethylene deformation;" "polyethylene worn;" and "pain, limited mobility, knee swelling, and sensitivity due to loose joint."

39. Upon information and belief, in 2013, complaints continued to be reported. Additional examples included: "revision for tibial loosening just two years postoperatively;"

"revision due to tibial loosening;" "during revision, the tibial component was found to be loose and easily removed;" "revision of knee component due to loosening;" and "revision due to pain and loosening."

40. Upon information and belief, the complaints of early onset failures continued in 2014. Examples further included: "revision due to tibial loosening;" "tibial loosening;" "revision of Optetrak knee components due to tibial loosening;" "revision due to pain and loosening;" and "revision of Optetrak knee components reportedly due [to] aseptic loosening."

41. The general practice in orthopedic implant surgeries, and with Exactech implants specifically, is for the sales representative of the manufacturer (hereinafter the "sales reps"), to be present at the time of surgery to provide implant components to the surgeon, thus relieving the hospital of the responsibility for having on stock all potential sizes and components that may be needed in surgeries. This practice of having a sales representative present applies to both the original implant surgery and any revision surgery.

42. The sales reps of Exactech observed many instances of premature failures of the Devices with plain evidence upon revision of polyethylene debris that needed to get removed, a/k/a "debrided." Additionally, sales reps observed injuries such as visible bone loss, osteolysis, and/or plainly loose components that were easy to remove due to lack of fixation. Often these sales reps would take the component from the surgeon to return to the company for inspection and analysis.

43. The sales reps of Exactech were under a duty to report these findings to the engineering and medical departments of Exactech who were in turn under a duty to do an investigation, analyze the removed component when available (i.e., "retrieval analysis"), and then honestly and thoroughly report such findings to the FDA and the surgeons.

44. Despite Defendants' knowledge of early onset failures of the Devices, Defendants

continued to manufacture, promote, and distribute the Devices without alerting surgeons, patients, or the FDA of the potential increased risks of early onset failures.

45. Defendants never changed the labeling, marketing materials, or product inserts to adequately and accurately warn patients or physicians of the associated increased risks of early failure due to loosening and/or polyethylene wear.

46. Furthermore, despite evidence indicating the Optetrak Device performed poorly, sales representatives observing an alarming trend of revisions due to wear and loosening, and international data identifying the Optetrak as an implant with a higher-than-expected rate of revision, instead of making design changes, Defendants chose to expand its product line again utilizing the 510(k) process to begin selling its newer Truliant design which "maintained many of the proven design features of the Optetrak and Optetrak Logic Knee Systems to help minimize contact stresses at the articular surfaces between the femoral and tibial components, thus lowering the potential for surface damage and wear." *See* https://www.exac.com/wp-content/uploads/2019/05/12-0000131_Rev A_Truliant_Design_Rationale_Web.pdf.

47. In fact, while knowing the Optetrak Device failed to meet the "superiority" or even a "non-inferiority" benchmarks as set forth by the International Benchmarking Working Group and Australian Orthopaedic Association, Defendants went on to represent the Truliant as continuing "to use the gold standard on the market as its predecessors have for many years…" *Id.*

48. In said publication, Defendants marketed the Truliant as having "polyethylene tibial inserts are molded individually…resulting in the component being more resistant to oxidation and therefore wear." *Id.*

49. Defendants made such representations despite admitting "there is little to no clinical history on these…" but represented the Truliant Device as safe and effective merely because it

derived from "an evolution of the Optetrak lineage which has demonstrated excellent long-term outcomes" without acknowledging known evidence of unreasonably high failure rates. *Id.*

50. On August 30, 2021, Defendants issued a partial recall of all Optetrak All-polyethylene tibial components, including the OPTETRAK All-polyethylene CC Tibial Components; OPTETRAK All-polyethylene CR Tibial Components; OPTETRAK All-polyethylene CR Tibial Sloped Components; OPTETRAK All-polyethylene PS Tibial Components; OPTETRAK HI-FLEX PS Polyethylene Tibial Components; OPTETRAK Logic All-polyethylene CR Tibial Components; OPTETRAK Logic All-polyethylene CRC Tibial Components; OPTETRAK Logic All-polyethylene PSC Tibial Components; OPTETRAK Logic Modular PS Tibial Components; OPTETRAK Logic RBK PS Tibial Components; TRULIANT CR Tibial Inserts; TRULIANT CRC Tibial Inserts; TRULIANT PS Tibial Inserts; and TRULIANT PSC Tibial Inserts.

51. In issuing the August 2021 recall, Defendants stated "inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer." *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266

52. According to the FDA website, "Exactech began notification to distributors and sales representatives on about 08/30/2021 via letter titled "URGENT MEDICAL DEVICE RECALL." Actions being taken by Exactech included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months. Phase 1: immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2: between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not

packaged in EVOH/Nylon bags." *Id.*

53. Despite initial communications with distributors and sales representatives, Defendants did not issue any communications to surgeons who had implanted Optetrak or Truliant Devices with the recalled polyethylene component, or to patients who had received an Optetrak or Truliant Device with a recalled polyethylene component until months later in February 2022.

54. On February 7, 2022, Defendants issued an "Urgent Medical Device Correction" in which it informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

See https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf

55. The "Urgent Medical Device Correction" went on to further state that Defendants were expanding the recall to include all knee arthroplasty polyethylene inserts packaged in non-conforming bags regardless of label or shelf life. The components subject to the recall now included: OPTETRAK®: All-polyethylene CR Tibial Components, All-polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRAK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; and TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts. *Id.*

56. It is estimated that a total of 147,732 inserts implanted in the United States since 2004 were produced with non-conforming packaging. *Id.*

57. Defendants further acknowledged the original Optetrak knee system has shown statistically significant higher overall revision rates compared to other total knee arthroplasties in the Australian, United Kingdom, and New Zealand joint registries. *Id.*

58. Specifically, reasons for revision associated with polyethylene wear, including loosening, osteolysis, and pain, were increased three-to seven-fold with the Optetrak total knee replacement combination of the Optetrak-PS/Optetrak according to the 2021 Australian National Joint Replacement Registry with revision diagnoses related to accelerated polyethylene wear possibly related to the non-conforming packaging. *Id.*

59. Implanting surgeons were advised in the February 2022 notice to contact patients previously implanted with recalled components and to schedule an evaluation if the patient is experiencing any new or worsening knee swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in the knee. *Id.*

60. Furthermore, Defendants advised surgeons that revision surgery should be considered for patients who exhibit premature polyethylene wear. *Id.*

61. Based on Defendants' own representations, since 2004, Defendants manufactured, promoted, and distributed the Devices without ensuring the polyethylene components were properly packaged to prevent or minimize oxidation. At no point, until August 2021, did Defendants first modify the packaging to address this defect.

62. In approximately 2017 – 2018, Exactech, Inc. was in the process of being acquired by the Private Equity Group TPG Capital, which in February 2018, successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of

Exactech. In connection with the transaction, Exactech's founders, CEO, and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/

63. Disclosure of knowledge of the improper packaging and excessive premature failure rates could have harmed this transaction.

64. At all times relevant to this action, Defendants were aware of the Truliant Devices' propensity to undergo substantial early polyethylene wear consisting of the degradation and breakdown of the plastic chemicals causing toxicity to the tissue and bone, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery and its attendant complications in patients.

65. At all times relevant to this action, Defendants failed to acknowledge the manufacturing defects in the Optetrak and Truliant Devices due to poor and inadequate quality assurance procedures and a wanton and reckless disregard for public safety. Defendants also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring, and quality assessments to ensure the safety of the Devices.

66. At the time the Optetrak and Truliant Devices were manufactured and sold to patients, including Plaintiff, the Devices were defectively manufactured, packaged, unreasonably dangerous, and did not conform to the federal regulations subjecting patients to unreasonable risks of injury.

67. At all times relevant to this action, Defendants' inadequate manufacturing processes also led to material flaws in the quality systems at its manufacturing, packaging, storage, and distribution facilities.

68. During the course of manufacturing and distributing the Devices, Defendants failed in several ways, including, without limitation, by:

a. failing to conduct adequate mechanical testing, including oxygen-resistance or other wear testing for the components, subassemblies, and/or finished Devices;

b. failing to test an adequate number of sample Devices on an ongoing basis;

c. failing to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. failing to identify and/or note the significance of any testing that resulted in failure of the Devices;

e. failing to take corrective actions to eliminate or minimize further failures of the Devices;

f. failing to adequately explain packaging specifications for the components, subassemblies, and/or finished Devices;

g. failing to perform adequate quality control before the components, subassemblies, and/or finished Devices were distributed;

h. failing to properly address reports from their sales representatives who reported their observations while attending revision surgeries where evidence of polyethylene debris and osteolysis was apparent and noted by the surgeons and the sales representatives themselves;

i. failing to timely implement corrective action and investigations to understand the root cause of these failures while continuing to sell the

components knowing they would be implanted into the bodies of thousands of people; and

j. becoming aware of the potential cause or causes but unreasonably avoiding informing patients and surgeons and delaying the ability to minimize damages as the devices continued to degrade and do damage in the patients' bodies.

69. On or before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known the Truliant Devices were failing and causing serious complications after implantation in patients. Such complications included, but were not limited to, catastrophic polyethylene wear including the deposition of plastic particulate wear debris throughout the knee, a high rate of component loosening, and overall early system failure resulting in tissue destruction, osteolysis, and other injuries causing severe pain, swelling, instability, and dysfunction in the knee and leg necessitating revision surgery.

70. Defendants as manufacturers of orthopedic devices know that each surgery, especially a revision surgery, is always more complicated than an initial knee replacement surgery, and is fraught with serious risks of infection, anesthesia errors, dislocations, and other serious complications that should be avoided.

71. Defendants, however, ignored reports of early failures of their Devices and failed to promptly investigate the cause of such failures or issue any communications or warnings to orthopedic surgeons and other healthcare providers.

72. Before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known that the Truliant Devices were defective and unreasonably dangerous to patients, that the products had an unacceptable failure and complication rate, and that the products

had a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

ANGELA OBERSTER'S IMPLANTS AND REVISION SURGERY

73. On September 26, 2017, Plaintiff ANGELA OBERSTER underwent a right total knee replacement surgery and was implanted with a 3.5/9 mm Exactech Truliant PS polyethylene Tibial Insert (Ref #: 02-022-35-3509, Lot #:4832570) at the Crystal Clinic Orthopaedic Center in Akron, Ohio.

74. On or about December 22, 2020, Plaintiff underwent a painful and risky right total knee revision surgery at The Crystal Clinic Orthopaedic Center which included removal of the failed polyethylene liner due to a "failed right total knee replacement."

75. During Plaintiff's revision surgery, Plaintiff's orthopedic surgeon encountered "inflammatory hypertrophy of the synovial lining" as well as a moderate amount of "synovial fluid." The polyethylene liner was removed, and a synovectomy was carried out.

76. Defendants, through its affirmative misrepresentations and omissions, actively and fraudulently concealed from Plaintiff and Plaintiff's health care providers the true and significant risks associated with the Truliant Device and the need to vigilantly do diagnostic procedures to promptly diagnose the insidious process of the toxic polyethylene particles degrading and causing osteolysis.

77. Defendants know that after the one-year checkup following a total knee arthroplasty, typically patients are not expected to return for monitoring absent problems. Thus, Defendants knew that unless they informed surgeons to call their patients back for periodic radiologic monitoring, polyethylene chemical degradation and attendant osteolysis could be

occurring unchecked until it reached the stage of severe bone loss.

78. As a direct, proximate, and legal consequence of the defective nature of the Truliant Device as described herein, Plaintiff ANGELA OBERSTER has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

79. As a further direct, proximate, and legal consequence of the defective nature of the Truliant, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

TOLLING OF STATUTE OF LIMITATIONS
(Ohio Rev. Code § 2305 (B) (1))

80. Pursuant to Ohio Rev. Code § 2305.10 (B) (1), Plaintiff sustained bodily injury that "did not manifest itself immediately" that was caused by the "exposure to hazardous or toxic chemicals….or ethical medical devices."

81. The breakdown and wear of polyethylene, a plastic, leads to the release of toxic compounds, including chemical additives and nanoplastics. *See* Rillig, Matthias C. *et al.*, "The Global Plastic Toxicity Debt," *Environ. Sci. Technol.* 2021, 55, 2717-2719.

82. All plastics contain additional chemicals or additives and may contain impurities such as catalyst residues, unreacted monomers, or breakdown products which possess toxic properties that can adversely affect human health. *Id.*

83. A comparison of muscle tissue from patients implanted with ceramic liners versus polyethylene liners during total hip arthroplasty demonstrated decreased osteolysis and capsule

atrophy as well as less structural change to the muscles. *See* Hernigou, Phillippe *et al.*, "Ceramic-on-ceramic THA Associated With Fewer Dislocations and Less Muscle Degeneration by Preserving Muscle Progenitors," *Clin Orthop Relat Res* (2015) 473:3762-3769.

84. In patients who develop osteolysis, there is osteolysis-associated reduced bone regenerative capacity with a decrease in mesenchymal stem cells (MSCs) that is accompanied by reduced muscle mass and increased fatty degeneration. *Id.*

85. For polyethylene implants with resulting osteolysis, a "possible mechanism was evaluated by an experimental study demonstrating that contact PE (polyethylene) particles inhibit the osteogenic activity of osteoprogenitor cells… which may result in reduced periprosthetic bone regeneration." *Id.*

86. To date, most plastic chemicals remain unknown and the toxic hazards of potentially thousands of chemicals humans are exposed to remain unknown, and thus, unregulated. *See* Zimmerman, Lisa *et al.*, "Plastic Products Leach Chemicals That Induce *In Vitro* Toxicity under Realistic Use Conditions," *Environ. Sci. Technol.* 2021, 55, 11814-11823.

87. Plastics contain several thousand extractable chemicals which induce *in vitro* toxicity. *Id.*

88. "Our study highlights that plastic products leach chemicals triggering toxicity… the prevalent antiandrogenicity is an indicator for the leaching of endocrine-disrupting chemicals relevant for human health. Our results also show that many more chemicals are migrating from plastics than previously known." *Id.*

89. Furthermore, gamma-sterilized ultra-high molecular weight polyethylene contains macroradicals that will react with available oxygen in air or dissolved in bodily fluids. Kurtz, Steven M., *UHMWPE Biomaterials Handbook*, "Packaging and Sterilization of UHMWPE"

(2016).

90. By virtue of Defendants' recall notice and representations on their website, Defendants describe a process by which sterilization of the tibial insert is achieved by gamma radiation in a reduced oxygen environment by use of oxygen barrier packaging. *See* https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf; "Optimizing Polyethylene Materials to the Application: When it Comes to Manufacturing Methods, Hips are Not Knees," *available at* https://www.exac.com/optimizing-polyethylene-materials-to-the-application/ (March 14, 2017).

91. "Gamma sterilization… initiate[s] a complex cascade of chemical reactions in the polymer, which ultimately result[s] in oxidation and subsequent degradation of material properties." *See UHMWPE Biomaterials Handbook.*

92. To the extent Defendants assert any limitations Defense that Plaintiff's cause of action accrued prior to her revision surgery, the statute of limitations period ought to tolled pursuant to Ohio Rev. Code § 2305.10 (B) (1) because Plaintiff could not have been informed by competent medical authority, or otherwise become aware, by the exercise of reasonable diligence that she had been injured as a result her polyethylene insert being "packaged in out-of-specification vacuum bag lacking a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance" leading to premature failure and wear which was only first revealed to Plaintiff, the public, and the medical community when Defendants issued the February 7, 2022 recall and admitted such facts.

93. Furthermore, the statute of limitations period ought to be tolled under principles consistent with "equitable and policy considerations" because Defendants through its affirmative misrepresentations and omissions, actively and fraudulently concealed from Plaintiff and

Plaintiff's healthcare providers the true and significant risks associated with the Device. *See O'Stricker v. Jim Walter Corp.,* 4 Ohio St. 3d 84, 447 N.E.2d 727 (1983).

94. Following implantation of the Device, Plaintiff and Plaintiff's healthcare providers relied on Defendants' continued representations that the Devices had excellent long-term clinical outcomes.

95. Defendants made these representations with knowledge of their falsity given their knowledge of reports of high failure rates.

96. As early as 2007, the Australian Joint Registry identified the Optetrak Device as having a higher than anticipated rate of revision.

97. According to the Australian Joint Registry published in 2007, use of the Optetrak-PS femoral component with an Optetrak tibial component resulted in a 6.23% revision rate at three years and 6.64% revision rate at four years. The Registry identified use of these components as "Individual Primary Total Knee Prostheses with higher than anticipated revision rates either alone or in combination."

98. The cumulative rate of revision with use of the Optetrak-PS femoral component and an Optetrak tibial component continued to increase. Data from the 2008 and 2009 Australian Joint Registry demonstrated a revision rate of 6.7% and 7.0% at five years, respectively.

99. By 2010, the use of the Optetrak-PS femoral component and Optetrak-PS tibial components were "identified and no longer used" as a result of a 21% cumulative revision rate at five years. This rate increased to 22.7% the following year.

100. Identification of problems with the Optetrak-PS tibial component continued to grow. According to the 2015 registry data, "[t]he Optetrak PS all-polyethylene prosthesis has a cumulative percent revision of 19.4% at seven years."

101. Defendants continued to make such representations despite later acknowledging, "[e]very Exactech Optetrak TKR polyethylene component combination demonstrated statistically significant increased revision rates compared to other TKR systems," citing 2021 Australian Registry data, however, data demonstrating high rates of premature failure were available to Defendants as early as 2007. *See* https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf

102. The Optetrak Device had similarly high failure rates as documented in the United Kingdom National Joint Registry. In 2015, the revision rate for the Optetrak Device was 5.02% at seven years and 6.92% at ten years. In 2016, the revision rate for the Optetrak Device was 5.15% at seven years and 7.79% at ten years. In 2017, the revision rate for the Optetrak Device was 5.23% at seven years and 7.45% at ten years. In 2018, the revision rate for the Optetrak CR was 5.53% at seven years and 7.61% at 10 years.

103. The failure rates for the Optetrak Device in the UK Registry were consistently higher compared to other knee replacement devices.

104. Despite such data, Defendants developed the Truliant and went on to represent the Truliant Device as safe merely because it derived from "an evolution of the Optetrak lineage which has demonstrated excellent long-term outcomes" without acknowledging known evidence of unreasonably high failure rates. *Id.*

105. Defendants sold these implants worldwide and had a duty to monitor the international registries to assess how their prostheses were faring. Unfortunately, since the United States does not have a single payor health system, there is no national registry and doctors in the Unites States are not privy to nor expected to be aware of such data from other continents.

106. Defendants never informed physicians of the high failure rates associated with the

Devices reported annually in the international registries.

107. Although clinical evidence demonstrated that Optetrak Devices were failing at a rate higher than promoted with instances of excessive revision rates due to device loosening and polyethylene wear, Defendants failed to initiate a recall earlier or issue any communications to healthcare providers that patients should be monitored. Rather Defendants expanded their inventory to market and sell to the public the Truliant Device, which later would be recalled for being prone to the same method of failure as the Optetrak.

108. Furthermore, earlier disclosure of these failure rates could have impacted the sale of the company to private equity.

109. Had Defendants not actively and fraudulently concealed evidence of growing reports of premature device failures, Plaintiff would have obtained radiological intervention at an earlier time.

110. Such intervention would have led to an earlier diagnosis of bone loss and earlier removal of the Device thereby reducing damage to bone and tissue.

111. As a result of Defendants' actions, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the result of defects in the product due to Defendants' acts, omissions, and misrepresentations.

112. Accordingly, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described herein.

CAUSES OF ACTION
VIOLATION OF THE OHIO PRODUCTS LIABILITY ACT ("OPLA")

(Ohio Rev. Code §§ 2307.71, *et seq*)

113. Plaintiffs plead the following Causes of Action under all applicable Products Liability Acts, and laws of Plaintiffs' resident state of Ohio, including the Ohio Products Liability Act ("OPLA"), Ohio Rev. Code §§ 2307.71, *et seq.*

FIRST CAUSE OF ACTION
STRICT LIABILITY – MANUFACTURING DEFECT
(Ohio Rev. Code § 2307.74)

114. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

115. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

116. The Defendants had a duty to manufacture the Truliant Device in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff.

117. The Defendants had a duty to distribute, market, and/or sell the Truliant Device without manufacturing and related packaging defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff.

118. The Truliant Device manufactured by the Defendants was not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

119. The Truliant Device was not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by the Defendants.

120. The defects in manufacture of the Truliant Device were a substantial factor in causing Plaintiff's injuries.

121. At all times herein mentioned, the Defendants tested, studied, researched, designed,

formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device, which was implanted in Plaintiff, such that these device was dangerous, unsafe, and defective in manufacture. The defects in manufacture include but are not limited to:

a. failure to package the polyethylene components of the Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

b. the materials used to package the Device were of an inferior grade or quality;

c. that the Device as manufactured differed from Defendants' intended specifications;

d. that Defendants failed to measure and/or test an adequate number of samples of Device on an ongoing basis;

e. that Defendants failed to take corrective actions to eliminate or minimize further failures of the Device;

f. that Defendants failed to perform adequate quality control or other such testing on the polyethylene inserts used in the Device to ensure they complied with required specifications and were not prematurely degrading while stored;

g. failing to select appropriate third-parties to package the polyethylene inserts used in the Device;

h. failing to properly supervise and monitor the packaging of the polyethylene inserts used in Device;

i. that Defendants failed to exercise sufficient quality control to ensure the polyethylene inserts in the Device were safe for implantation in users and patients and would not degrade abnormally under average and regular use; and

j. that Defendants violated applicable state and federal laws and regulations; and in all other ways.

122. Defendants knew or reasonably should have known and been aware that the Truliant Device was defectively manufactured.

123. The manufacturing defects in the Device existed when it left the Defendants' control.

124. Plaintiff's physician implanted the Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

125. The Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

126. As alleged herein, Defendants knew or had reason to know that the Device caused an increased risk of harm to the Plaintiff and other consumers due to the devices' propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need

for revision surgery in patients.

127. The manufacturing defects of the Truliant Device presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

128. The manufacturing defects of the Truliant Device presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when the Device was used and operated in a manner that was foreseeable to Defendants.

129. Plaintiff could not, by the exercise of reasonable care, have discovered the manufacturing defects and perceived the dangers or avoided injury.

130. The Defendants are strictly liable for the defective manufacture of the Truliant Device; the distribution, marketing, and/or sale of the defectively manufactured Truliant Device; and the injuries sustained by Plaintiff.

131. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

132. By reason of the foregoing acts, omissions, and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

133. As a direct, proximate, and legal consequence of the defective nature of the Truliant Device as described herein, Plaintiff ANGELA OBERSTER has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue

damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

134. As a further direct, proximate, and legal consequence of the defective nature of the Devices, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

135. The harm suffered was the result of Defendants' misconduct of which manifested a "flagrant disregard for the safety of persons who might be harmed by the product in question," entitling Plaintiffs to punitive damages pursuant to Ohio Rev. Code § 2307.80.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT
(Ohio Rev. Code § 2307.75)

136. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

137. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

138. Defendants had a duty to design and package the Truliant Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

139. Defendants had a duty to distribute, market, and/or sell the Truliant Device with a

design that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

140. The design of the Truliant Device, and corresponding packaging, is defective and not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

141. The Truliant Device and corresponding packaging was not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendants.

142. The defective design of the Truliant Device and packaging received by Plaintiff's implanting surgeon were a substantial factor in causing Plaintiff's injuries.

143. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device, which were implanted in Plaintiff, such that it was dangerous, unsafe, and defective in design. The defects in the design include but are not limited to:

a. that the Device has a propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients;

b. failure to design the packaging for the polyethylene components of the Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis,

and other injuries as well as the need for revision surgery;

c. that the materials used within the Device and packaging were of an inferior grade or quality than advertised and promoted by Defendants;

d. Defendants failed to conduct adequate testing, including wear or other testing, on components, subassemblies and/or the finished Device as packaged and distributed;

e. Defendants failed to test an adequate number of samples of the Device on an ongoing basis;

f. Defendants failed to take adequate steps to specifically identify failure modes with the Device with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

g. Defendants failed to identify and/or note the significance of any testing that resulted in failure of the Device;

h. Defendants failed to take corrective actions to eliminate or minimize further failures of the Device;

i. Defendants failed to adequately design packaging specifications for the components, subassemblies, and/or the finished Device;

j. The polyethylene material used in the Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a higher failure rate than other similar devices available at the time the Devices were put on the market;

k. The polyethylene material used in the Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a

shorter effective lifetime than other similar devices available at the time the Devices were put on the market;

l. The Defendants' method of designing the polyethylene insert and packaging increased the risk of users and patients suffering from pain, discomfort, injury, and the need for revision surgery; and

m. that Defendants violated applicable state and federal laws and regulations; and in all other ways.

144. Defendants knew or reasonably should have known and been aware that the Truliant Device and packaging were defectively designed.

145. The design defects in the Truliant Device and packaging existed when the devices left the Defendants' control.

146. Plaintiff's physician implanted the Truliant Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

147. The Truliant Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in condition.

148. As alleged herein, Defendants knew or had reason to know that the Truliant Device caused an increased risk of harm to the Plaintiff and other consumers due to the devices' propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

149. The Truliant Device and packaging as designed carried risks that were outweighed by any utility of the design of the devices and packaging because when paired together the implants, the

Device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Device and the packaging in which it was received were in a condition not suitable for proper and intended use.

150. The Truliant Device and packaging were defective in design and unreasonably dangerous when the Device entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the Device.

151. Feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Devices were designed and packaged and offered for sale in the market.

152. For example, Defendants could have utilized vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) to prevent the polyethylene components from undergoing increased oxidation according to their own admissions.

153. The design defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

154. The design defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

155. Plaintiff could not, by the exercise of reasonable care, have discovered these design defects and perceived the dangers or avoided injury.

156. The Defendants are strictly liable for the defective design of the Truliant Device; defective design of the packaging of the Truliant Device; the distribution, marketing, and/or sale of the Truliant Device; and the injuries sustained by Plaintiff.

157. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

158. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

159. As a direct, proximate, and legal consequence of the defective nature of the Truliant Device as described herein, Plaintiff ANGELA OBERSTER has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

160. As a further direct, proximate, and legal consequence of the defective nature of the Devices, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

161. The harm suffered was the result of Defendants' misconduct of which manifested a "flagrant disregard for the safety of persons who might be harmed by the product in question," entitling Plaintiffs to punitive damages pursuant to Ohio Rev. Code § 2307.80.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

(Ohio Rev. Code § 2307.76)

162. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

163. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

164. Defendants had a duty to provide adequate warnings regarding the Truliant Devices in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

165. Defendants had a duty to distribute, market, and/or sell the Truliant Devices with adequate warnings that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

166. The warnings that accompanied the Truliant Device and corresponding packaging were defective thereby making the product not reasonably safe for their expected, intended, and/or foreseeable uses, functions, and purposes.

167. The Truliant Device and corresponding packaging were not reasonably safe as labeled, distributed, marketed, delivered and/or sold by Defendants.

168. Inadequate labeling accompanying the Truliant Device and packaging received by Plaintiff's implanting surgeon was a substantial factor in causing Plaintiff's injuries.

169. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device, which was implanted in Plaintiff, such that

it was dangerous, unsafe, and defective.

170. The Truliant Device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants, or its sales force, to physicians and patients failed to adequately convey the potential risks and side effects of the Device and the dangerous propensities of the Devoce, which risks were known or were reasonably scientifically knowable to Defendants.

171. In particular, Defendants failed to adequately disclose the Devices' propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, bone loss, osteolysis, and other injuries as well as the need for revision surgery in patients.

172. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Truliant Devices; and continuing to market, promote, sell, and defend the Truliant Devices until the very recent recall.

173. Defendants knew or reasonably should have known and been aware that the Truliant Device and packaging contained inadequate warnings.

174. The inadequate warnings for the Truliant Device existed when the Device left the Defendants' control.

175. Plaintiff's physician implanted the Truliant Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

176. The Truliant Device as tested, studied, researched, designed, formulated,

manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

177. As alleged herein, Defendants knew or had reason to know that the Devices caused an increased risk of harm to the Plaintiff and other consumers due to the devices' propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

178. The Truliant Device that was labeled, manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user, or ordinary consumer of the device, including Plaintiff.

179. The labeling defects of the Truliant Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

180. The labeling defects of the Truliant Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when it was used and operated in a manner that was foreseeable to Defendants.

181. Plaintiff could not, by the exercise of reasonable care, have discovered these defects and perceived its dangers or avoided injury.

182. Defendants failed to issue new warnings or initiate a recall in a timely manner as to help minimize the damage and bone loss occurring in patients, including Plaintiff.

183. The Defendants are strictly liable for providing inadequate warnings accompanying the Truliant Device and packaging of the Truliant Device; the distribution, marketing, and/or sale of the Truliant Device; and the injuries sustained by Plaintiff.

184. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

185. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

186. As a direct, proximate, and legal consequence of the defective nature of the Truliant Device as described herein, Plaintiff ANGELA OBERSTER has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

187. As a further direct, proximate, and legal consequence of the defective nature of the Truliant Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

188. The harm suffered was the result of Defendants' misconduct of which manifested a "flagrant disregard for the safety of persons who might be harmed by the product in question," entitling Plaintiffs to punitive damages pursuant to Ohio Rev. Code § 2307.80.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
NEGLIGENCE

(Ohio Rev. Code §§ 2307.71(A)(13))

189. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

190. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

191. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Truliant Device for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

192. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution, and sale of the Truliant Device.

193. Following Plaintiff's initial knee surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in failing to recall the Truliant Devices.

194. At all times material hereto, the Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with the Truliant Devices.

195. Defendants had access to registry data and were aware of complaints that the

Truliant Devices caused serious complications including but not limited to polyethylene wear and/or other failure causing serious complications including component loosening, tissue damage, osteolysis, bone loss and the need for revision surgery in patients.

196. Despite the fact Defendants knew or should have known the Truliant Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Device for implantation into consumers.

197. Despite the fact Defendants knew or should have known the Truliant Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Device for implantation into consumers without revising any warning language or issuing an earlier recall.

198. Defendants failed to advise surgeons and patients of the need for regular follow-up beyond the ordinary practices after a total knee implant as to promptly detect polyethylene degradation and osteolytic failure and timely revise the device to prevent or at least minimize bone loss, osteolysis, and related injuries.

199. Defendants failed to exercise due care under the circumstances, and their gross negligence and recklessness includes the following acts and omissions:

a. Negligently failing to properly package the polyethylene components of the Device;
b. Negligently failing to select appropriate third-parties to package the polyethylene inserts used in the Device;
c. Negligently failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Device;
d. Negligently failing to properly and thoroughly select the material that would be

used in the packaging of the Device;

e. Negligently failing to properly and thoroughly select the materials that would be used in the Device;

f. Negligently failing to properly and adequately test the Device and its attendant parts before releasing the devices to market;

g. Negligently failing to conduct sufficient post-market testing and surveillance of the Device;

h. Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Device in accordance with good practices;

i. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Device;

j. Continuing to negligently manufacture, and distribute the Device after the Defendants knew or should have known of its adverse effects and/or the increased early onset failure rates;

k. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Device to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Device;

l. Negligently failing to notify and warn the public, including Plaintiff, and physicians of reported incidents involving injury and the negative health effects attendant to the use of the Device;

m. Negligently misrepresenting the safety of the Device;

n. Negligently failing to provide warnings, instructions or other information that

accurately reflected the risks of early failure of the Device;

o. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Device;

p. Negligently failing to exercise due care in the advertisement and promotion of the Device;

q. Negligently disseminating information that was inaccurate, false, and misleading which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Device;

r. Aggressively promoting the Device without proper warnings of the risk of early failure or material degradation in the average user;

s. Aggressively promoting the Device even after Defendants knew or should have known of the unreasonable risks from implantation;

t. Negligently failing to warn consumers, doctors, users and patients that the Device would contain polyethylene materials not properly packaged and/or in accordance with Defendants' specifications;

u. Negligently diminishing or hiding the risks associated with the implantation of the Device;

v. Negligently failing to recall the Devices at an earlier date and institute a process to have patients notified; and

w. Negligently violating applicable state and federal laws and regulations; and in all other ways.

200. Defendants knew and/or should have known that it was foreseeable that consumers

such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Implants, and otherwise distributing the Truliant Device.

201. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

202. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

203. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Truliant Device, Plaintiff ANGELA OBERSTER was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

204. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution the Truliant Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

205. The harm suffered was the result of Defendants' misconduct of which manifested

a "flagrant disregard for the safety of persons who might be harmed by the product in question," entitling Plaintiffs to punitive damages pursuant to Ohio Rev. Code § 2307.80.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(Ohio Rev. Code §§ 2307.71(A)(13))

206. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

207. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

208. Defendants owed a duty to orthopedic surgeons, other healthcare providers, and to consumers of the Truliant Device, including Plaintiff, to accurately and truthfully represent the risks of the Device. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's orthopedic surgeon, the medical community, Plaintiff, and the public about the risks of the Device, including the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, which Defendants knew, or in the exercise of diligence should have known.

209. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Devices knew, or reasonably should have known, that health care professionals

and consumers of the Truliant Device would rely on information disseminated and marketed to them regarding the products when weighing the potential benefits and potential risks of implanting the Devices.

210. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Truliant Device knew, or reasonably should have known, that the patients implanted with the Devices would suffer early failure and require revision surgery because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

211. The Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the quality and longevity of the Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

212. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the Devices were safe, had an excellent performance record, and did not have a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

213. Despite their knowledge of serious problems with the Optetrak and Truliant Devices, Defendants urged their sales representatives to continue marketing the Devices, and distributed medical literature, white papers, non-peer reviewed studies, and other communications to surgeons in an effort to mislead them and the general public about the risks associated with the Devices and instead create the image and impression that the Devices were safe.

214. Defendants made such statements even after they became aware of numerous and serious complications with the Devices. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data.

215. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Truliant Device.

216. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

217. Misrepresentations spanned a number of years, but also include the critical time period of 2017 – 2018 when the company was in the process of being acquired by the Private Equity Group TPG Capital which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/

218. Full disclosure of the magnitude of the problem with the polyethylene failure might have negatively impacted the merger prospects and the merger may have been one of the reasons the problems were concealed.

219. Nevertheless, after the merger in 2018, it still took four years for Defendants to reveal the product defects and their health consequences to the medical community and to the patients, including Plaintiff, even though the key officers of Exactech generally continued with their roles in the newly merged company.

220. Defendants failed to exercise ordinary care in making their representations

concerning the Truliant Device, and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Device.

221. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

222. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

223. As a direct and proximate result of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Truliant Device herein, Plaintiff ANGELA OBERSTER was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

224. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Truliant Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

225. The harm suffered was the result of Defendants' misconduct which manifested a "flagrant disregard for the safety of persons who might be harmed by the product in question," entitling Plaintiffs to punitive damages pursuant to Ohio Rev. Code § 2307.80.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and

punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Ohio Rev. Code § 2307.77)

226. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

227. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

228. Defendants expressly warranted the Optetrak and Truliant Devices, including the Optetrak Logic Comprehensive Knee System and Truliant PSC Knee System, were safe and effective orthopedic devices.

229. Defendants promised that the Devices had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

230. Defendants expressly warranted, despite admitting there was "little clinical history on the these," that the Truliant's "polyethylene tibial inserts are molded individually…resulting in the component being more resistant to oxidation and therefore wear."

231. At the time Defendants manufactured, marketed, sold and/or distributed the Devices, they knew that the Truliant Device was intended for human use, and that Plaintiff was a foreseeable user of the Device.

232. The express warranties represented by Defendants were a part of the basis for

Plaintiff's use of the Truliant Device, and she and her surgeon relied on these warranties in deciding to use the Device.

233. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Truliant Device was to be used and warrantied the same to be in all respects safe, effective, and proper for such purpose.

234. The Truliant Device did not conform to these express representations as demonstrated by the fact that Plaintiff's implant failed prematurely which necessitated her to undergo revision surgery.

235. At the time Defendants marketed, sold and/or distributed the Devices, Defendants expressly warranted that the total knee replacement systems, including all of their component parts, were safe and merchantable for their intended use.

236. Plaintiff ANGELA OBERSTER and her implanting physician reasonably relied upon Defendants' express warranties.

237. Plaintiff ANGELA OBERSTER used the Truliant Device for its intended purpose and in a reasonably foreseeable manner.

238. The Truliant Device manufactured and sold by Defendants, did not conform to Defendants' express representations because the Device caused serious injury to Plaintiff when used as recommended and directed.

239. As a direct and proximate result of Defendants' acts and omissions, including breach of express warranty, Plaintiff ANGELA OBERSTER was implanted with the Truliant Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

240. As a further direct, proximate, and legal consequence of Defendants' acts and omissions, including breach of express warranty, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

241. The harm suffered was the result of Defendants' misconduct which manifested a "flagrant disregard for the safety of persons who might be harmed by the product in question," entitling Plaintiffs to punitive damages pursuant to Ohio Rev. Code § 2307.80.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Ohio Rev. Code § 2307.77)

242. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

243. Prior to Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

244. Defendants impliedly warranted, through its marketing, advertising, distributors, and sales representatives, that the Truliant Device was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

245. In fact, the Truliant Device was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

246. The Truliant Device manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the components to be properly packaged and stored as to avoid premature degradation of component materials.

247. Plaintiff ANGELA OBERSTER and/or her physician reasonably relied upon the skill and judgment of Defendants as to whether the Truliant Device was of merchantable quality and safe for its intended and particular use and purpose.

248. Contrary to such implied warranties, the Truliant Device was not of merchantable quality or safe for its intended and particular use and purpose, because Defendants failed to package the polyethylene components of the Device in vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

249. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Plaintiff ANGELA OBERSTER was implanted with the Truliant Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

250. As a further direct, proximate, and legal consequence of Defendants' acts and omissions, including breach of implied warranties, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

251. The harm suffered was the result of Defendants' misconduct which manifested a "flagrant disregard for the safety of persons who might be harmed by the product in question," entitling Plaintiffs to punitive damages pursuant to Ohio Rev. Code § 2307.80.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
LOSS OF CONSORTIUM AND SERVICES

252. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

253. At all relevant times, Plaintiff DONALD OBERSTER was and is the lawfully wedded husband of Plaintiff ANGELA OBERSTER, and as such, was and is entitled to the services, consortium, and society of ANGELA OBERSTER.

254. As a result of the foregoing, Plaintiff DONALD OBERSTER was deprived of the services, consortium, and society of ANGELA OBERSTER.

255. As a direct, proximate, and legal consequence of Defendants' wrongful conduct described herein, Plaintiff DONALD OBERSTER has suffered and will continue to suffer the loss of support, companionship, service, love, affection, society, intimate relations and other elements of consortium all to the detriment of their marital relationship for which Plaintiff DONALD OBERSTER is entitled to compensatory and equitable damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a. Judgment in favor of Plaintiffs and against all Defendants, for damages in excess of $75,000, the exact amounts to be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, loss of consortium, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees and costs;

e. Prejudgment and post-judgment interest; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

DATED: December 20, 2022

Respectfully submitted,

PLAKAS | MANNOS

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Counsel for Plaintiffs

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Plaintiffs demand trial by jury in the above captioned action on all issues so triable.

/s/ Brandon W. McHugh
Counsel for Plaintiffs